UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, ET AL., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	**MDL No 3026** **Master Docket No. 1:22-cv-00071** **Hon. Rebecca R. Pallmeyer**
This Document Relates to: ***Brown, et al. v. Abbott Laboratories, et al.*****, Case No 1:22-cv-02001**	
PLC's Response to Defendant's Motion to Exclude Dr. Logan Spector (ECF No. 60)	

I. Introduction

Plaintiffs designated Dr. Logan Spector as their epidemiology expert to offer a general-causation opinion on whether cow's-milk-based formula (CMBF) causes NEC in premature and low-birth-weight infants. He opined that exposure to preterm infant formula can cause NEC, with greater exposure increasing the risk. ECF No. 60-1 (Spector Rep.) at 3. He did not confine his opinion to infants fed a particular percentage of formula. Recognizing that his opinion was reliable and helpful to a jury, the Court rejected the exact argument Defendant makes here after the MDL-wide *Daubert* hearing on March 31, 2025.

According to the Court, "Dr. Spector's broad analysis of studies exploring a range of different feeding mixtures applies across the diverse feeding methods in the MDL cases." 1:22-cv-00071, ECF No. 646 (Order), PageID #29131. Based on this observation, the Court specifically held:

> [Dr. Spector] has instead explained that although a precise triggering exposure may not be ascertainable, the epidemiological literature does establish that a dose-response relationship likely exists between [cow's-milk-based formula] and NEC (more formula increases the likelihood of NEC).

Id. In other words, the Court rejected Defendant's contention that Dr. Spector must establish the precise threshold (or percentage of formula to human milk) an infant must consume to survive a motion to exclude.

Nevertheless, Abbott—in what can only be described as an untimely motion for reconsideration—argues yet again that Dr. Spector's opinion does not "fit" the facts of this case. According to Abbott, this is because a phantom issue it describes as "the right way to measure a preterm infant's exposure to formula" remains unresolved. ECF No. 60 (Def.'s Mtn. to Exclude) at 2. Abbott's argument is nonsensical—and Abbott knows it. Its original motion to exclude Dr. Spector referenced *both* the infant in *Mar* and the infant in this case, arguing that "[t]wo of the bellwether cases illustrate this point." 1:22-cv-00071, ECF No. 605 (Defs.' Mtn. to Exclude), PageID #14289. Recognizing the Court rejected this argument, Abbott litters its motion with efforts to unwind itself

from the Court's prior opinion. But those efforts do not overcome the fact that Abbott lost this precise argument at the *Daubert* hearing. The Court not only rejected this argument months ago (making it law of the case),[1] but also concluded that any dose-response issue does not make Dr. Spector's causation opinion "wholly inapplicable." No. 1:22-cv-00071, ECF No. 646 (Order), PageID #29130. Dr. Spector testified that he observed a causal association between diets with higher percentages of cow's-milk-based formula and NEC from a *qualitative* perspective.[2] The Court and the law agree that is sufficient *Id.* at PageID #29132.

II. Relevant Background

A. D.B. died of NEC within 48 hours of first formula exposure.

D.B. was born on July 7, 2021, at 24 weeks and 4 days gestational age, weighing 680 grams. ECF No. 60-2 (Flanigan Rep.) at 3–4. On July 9, 2021, he began trophic feeds of human donor milk. *Id.* Approximately one week later, on July 26, 2021, Prolacta, a human-milk-based fortifier, was added to D.B.'s donor-milk diet. *Id* at 5. Three days later, providers noted no sign of abdominal distension. *Id.* By August 21, 2021, D.B. was tolerating full feeds of human donor milk with Prolacta fortifier and was steadily gaining weight. *Id.* at 6.

After nine weeks of an exclusively human-milk/human-milk-based fortifier diet, on September 11, 2021, D.B. was transitioned to one daily feed of Similac Special Care 24 (SSC24), a CMBF manufactured by Abbott. *Id.* at 15–16. The next day, he was increased to two SSC24 feeds,

[1] See *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 332–33 (1979) (holding offensive collateral estoppel can be used by a plaintiff to prevent a defendant from litigating an issue defendant previously unsuccessfully litigated in another action with another party); *Bifolck v. Philip Morris USA Inc.*, 936 F.3d 74, 78 (2d Cir. 2019). *See also In re E. I. du Pont de Nemours & Co. C-8 Pers. Inj. Litig.*, 54 F.4th 912, 927 (6th Cir. 2022) (holding plaintiff may invoke offensive collateral estoppel if the issues are identical, the prior issue was actually litigated and actually decided, defendant had full and fair opportunity to litigate in prior proceeding, and prior issue litigated was necessary to outcome of prior case).

[2] 1:22-cv-00071, ECF No. 616-3 (Spector Tr. Vol. 1) at 286:19–22; 348:10–349:3.

followed by four SSC24 feeds on September 13, and then to full-volume SSC24 feeds on September 14. *Id.*

At 9:39 p.m. on September 15, 2021, within 24 hours of the introduction to full volume SSC24 feeds, D.B. presented with increased abdominal distention. *Id.* at 8. Less than ten hours later, on September 16, 2021, his condition worsened: continued abdominal distension, rigid abdomen, and no bowel sounds. D.B. was then diagnosed with fulminant NEC. *Id.* at 8, 23. By 10:30 p.m. that evening, despite medical intervention, D.B. tragically passed away. *Id.* at 9–10. This was just four days after his first formula feed and one day after full enteral feedings with SSC24. *Id.* at 23. Based on a review of his medical records, Dr. Flanigan, Plaintiff's specific-causation expert, concluded within a reasonable degree of medical certainty that cow's-milk-based formula was not only a substantial causative factor but was "the most important" contributing factor to D.B.'s NEC diagnosis. *Id.*

III. Law and Argument

The *Daubert* inquiry requires the court to "determine whether the evidence or testimony assists the trier of fact in understanding the evidence." *Deimer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 344 (7th Cir. 1995). Expert testimony must "fit" the issue to which the expert is testifying and have a "valid scientific connection to the pertinent inquiry." *Id.*; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 580 (1993). "If the proposed expert testimony meets the *Daubert* threshold of relevance and reliability, the accuracy of the actual evidence is to be tested before the jury with the familiar tools of 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 805 (7th Cir. 2012) (quoting *Daubert*, 509 U.S. at 596).

The reality is that Abbott's arguments "raise matters of weight rather than admissibility." Fed. R. Evid. 702, Adv. Comm. Notes, 2023 Amendments. Dr. Spector's opinions fit the facts of this case;

his analysis and methodology are relevant, reliable, and consistent; and his conclusions are helpful to the jury. Abbott's dissatisfaction with the substance of Dr. Spector's opinions cannot change that.

A. Just like in *Mar*, Dr. Spector's opinion fits the facts of this case and would be helpful to the jury.

1. Abbott's argument—a carbon copy of what it has already argued—was rejected long ago.

Contrary to Abbott's claim, Dr. Spector's opinion fits the facts of this case. In *Mar,* this Court denied Abbott's motion to exclude based on nearly identical facts and a completely identical argument. 1:22-cv-00071, ECF No. 646 (Order), PageID #29133. Refusing to accept defeat, Abbott attempts to shape-shift its argument into something more than it is—a doomed endeavor to exclude a well-reasoned, reliable, and relevant expert opinion. It must fail here, just as it did before.

Dr. Spector observed an association between NEC and diets consisting of higher percentages of cow's-milk-based formula from a qualitative perspective. ECF No. 60-1 (Spector Rep.) at 3; 1:22-cv-00071, ECF No. 616-3 (Spector Tr. Vol. 1) at 286:19–22; 348:10–349:3. His opinion was not constrained to a specific percentage of exposure. Instead, he opined that the more formula an infant receives, the greater the likelihood of contracting NEC. Abbott wholly ignores this opinion (as well as this Court's holding in *Mar*), claiming he must quantify the *precise dose* (or exposure to formula) an infant must consume to trigger NEC. There is no dispute the Court rejected this argument in *Mar*. 1:22-cv-00071, ECF No. 646 (Order), PageID #29131 ("In this case, Dr. Spector has not opined that 'any exposure' to [cow's-milk-based formula] causes NEC. He has instead explained that although a precise triggering exposure may not be ascertainable, the epidemiological literature does establish that a dose-response relationship likely exists between [cow's-milk-based formula] and NEC (more formula increases the likelihood of NEC)."); *Id.* at PageID #29132–33.

When it rejected Abbott's argument the first time, the Court made several important observations that are relevant here. First, in the Court's words, "[n]o case requires that Dr. Spector

reach beyond the available scientific literature and assert a threshold dose; it is sufficient that he discusses dose-response as it appears in the available studies." *Id.* at PageID #29132–33. Second, the Court recognized that "although a precise triggering exposure may not be ascertainable, the epidemiological literature does establish that a dose-response relationship likely exists between CMBF and NEC (more formula increases likelihood of NEC)." *Id.* at PageID #29131. Finally, the Court noted "Dr. Spector has not similarly conceded that certain diets are safe at a certain percentage of [cow's-milk-based formula], and the court does not read Judge Tharp's opinion [in *Zurbriggen v. Twin Hill Acquisition Co., Inc.*] as holding that expert epidemiological testimony as to dose-response is not reliable where threshold dose is not established in the literature." *Id.* at PageID #29133, n.21. These observations establish that Dr. Spector's opinion—that the risk of NEC increases as the exposure to formula increases—should not be excluded just because Dr. Spector did not define a dose-response threshold. Even without such a threshold, the opinion fits the facts of the case and will help the jury.

Abbott is not explicit in saying the Court was wrong in *Mar*, but that is the clear implication from its brief. But the Court's holding is not wrong—a fact Abbott underscores by premising the totality of its argument in this case on one lone citation.[3] There is simply no requirement that an expert identify the precise volume of formula an infant must consume to trigger NEC. *See generally In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2018 WL 4030585, at *5 (N.D. Ill. Aug. 23, 2018) (rejecting the exact argument Abbott makes because "[d]iscuss[ing] how certain studies suggest that higher doses of AndroGel pose greater CV risks" is sufficient to evidence dose); *Quirin v. Lorillard Tobacco Co.*, No. 13 C 2633, 2014 WL 716162, at *6 (N.D. Ill. Feb. 25, 2014) (holding plaintiff's

[3] That case, *Owens v. Auxilium Pharm., Inc.*, is readily distinguishable. The *Owens* expert, who was excluded, was a case-specific expert whose opinion was excluded because it was based on the assumption that the plaintiff used the subject drug as prescribed, when the plaintiff actually used less than prescribed. 895 F.3d 971, 973 (7th Cir. 2018). Here, Dr. Spector is a general-causation expert, discussing general dose-response from a qualitative perspective—the greater exposure to formula, the greater the risk of NEC. That is a far cry from a case-specific expert opinion premised on assumptions proven untrue.

expert was not required to identify precise level of asbestos in Kent cigarettes).[4] The law in this District is clear: qualitative evidence of dose-response is sufficient for a general-causation expert to proceed to the jury. Just as Dr. Spector cleared this hurdle in *Mar*, he clears it here.

B. General-causation experts are not required to opine on every potential fact pattern that could be implicated by individual cases in an MDL. Abbott's efforts to relitigate this issue should be estopped.

Abbott's entire argument seeks to relitigate the ruling in *Mar*, reopen the flood gates, and essentially ask for reconsideration of the Court's ruling not only on Dr. Spector's testimony, but also on the proper measurement of exposure. But Abbott cannot take a second bite at the apple simply because the first one did not suit its taste.

Offensive collateral estoppel applies when a plaintiff seeks to prevent a defendant from re-litigating an issue the defendant previously litigated unsuccessfully. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 (1979). The Supreme Court has granted district courts "broad discretion to determine when [this principle] should be applied." *Id.* at 331. There are four factors courts consider in determining if offensive collateral estoppel is appropriate: (1) whether the issue in the current proceeding is identical to the prior one; (2) whether the issue in the prior proceeding was actually litigated and decided; (3) whether defendants had a full and fair opportunity to litigate the issue; and (4) whether the issue previously litigated was necessary to the outcome of the prior case. *Bifolck v.*

[4] This District does not stand alone in its rejection of similar dose-response arguments. *See generally Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 25 (1st Cir. 2011) (court erred in excluding epidemiologist just because he "attempt[ed] to support his conclusion with data that concededly lack[ed] statistical significance," which was not "a deviation from sound practice of the scientific method that provided grounds for exclusion") (internal quotations omitted); *In re Abilify Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1330–31 (N.D. Fla. 2018) (finding anecdotal evidence of dose-response relationship relevant where "the ethical limitations inherent in human experimentation" required scientists to "rely on *in vitro* and *in vivo* animal studies to examine the relationship between dose and response"); *In re Tasinga Prods. Liab. Litig.*, No. 6:21-md-3006, 2024 WL 1343157, at *4 (M.D. Fla. Jan. 15, 2024) ("[A] trial is not unreliable just because it lacks a placebo arm—it might be unethical to give a human a placebo when it is known that an effective baseline drug exists.").

Philip Morris USA Inc., 936 F.3d 74, 79–80 (2d Cir. 2019); *In re E. I. du Pont de Nemours & Co. C-8 Pers. Inj. Litig.*, 54 F.4th 912, 923–26 (6th Cir. 2022).

The first prong of this test "is concerned not with claims or causes of action as a whole, but with *issues*—single, certain, and material points arising out of the allegations and contentions of the parties." *Bifolck*, 936 F.3d at 81 (cleaned up) (emphasis in original). This issue—the single, certain, and material point of whether Dr. Spector was required to establish a dose-response threshold—arose in Defendant's argument to exclude Dr. Spector in *Mar*. Defendant argues yet again that Dr. Spector's opinions are unhelpful to the jury because he could not opine as to the threshold dose at which formula increases the risk of NEC, making his opinions "wholly inapplicable." No. 1:22-cv-00071, ECF No. 605 (Defs.' Mtn. to Exclude) at 20. Here, Abbott's argument is identical: "Dr. Spector repeatedly confirmed that he has no opinion applicable to D.B." because he "didn't analyze the relative risk of NEC for a diet consisting of 90 percent human milk and 10 percent bovine-derived product." ECF No. 60 (Def.'s Mtn. to Exclude) at 1, 6 (cleaned up). Making the same argument in slightly different words does not amount to raising a new issue.

This issue was not only previously briefed in *Mar*, but was fully and vigorously litigated in a day-long *Daubert* hearing. Following that hearing, the Court issued a 40-page Order, which rejected that very argument. In other words, prongs two and three are satisfied: the issue was fully and fairly litigated before it was decided—against Defendant.

The fourth prong is aimed at protecting against unfairness by "ensuring that the issue was really disputed and that the loser… put out his best efforts." *Bifolck*, 936 F.3d at 82 (cleaned up). Abbott cannot possibly contest that the admissibility of Dr. Spector's opinion was undisputed in *Mar*. Unless Abbott intends to argue that it did not put forth its best efforts in the *Daubert* briefing and hearing for the entirety of this MDL, the fourth prong is clearly satisfied. And the *Daubert* issue at hand was necessary to the outcome of the litigation as whole. Dr. Spector's general-causation opinion

also served as the basis for Plaintiffs' other general-causation expert, Dr. Jennifer Sucre. If Dr. Spector's general-causation opinion was excluded, as Abbott contends it should be, then Plaintiffs would no longer have a general-causation expert to offer.[5] In other words, this issue was not only necessary, but potentially case-dispositive. Therefore, the fourth prong is satisfied. Holding Abbott to this Court's prior ruling and avoiding needlessly rehashing the same issues is not unfair to Abbott.

Application of offensive collateral estoppel in this case is only fair. *Bifolck*, 936 F.3d at 84; *In re E. I. du Pont*, 54 F.4th at 921–23. There are no procedural opportunities available in this case that were not available in *Mar*—the Court rejected Abbott's dose and measurement-of-exposure arguments not once (after the *Daubert* hearing), not twice (in excluding Dr. Makuch), but three times now (in issuing the September 2, 2025 minute order). Inserting the name of a different plaintiff does not make the substance of the argument any different, and it is a waste of the Court's time and the parties' resources to relitigate this issue anew with each MDL plaintiff. The Court has spoken: Dr. Spector is not required to opine on a precise triggering exposure and is permitted to discuss his opinion that a dose relationship exists between formula and NEC. Abbott should be estopped from making the same argument again and again with the hope of reaching a different result.

C. Even if a dose threshold were required, Dr. Spector's analysis includes literature establishing that even low levels of total exposure to formula can result in an increased risk of NEC.

Even if a general-causation expert's opinion was required to address the specificities of each and every case subsumed within an MDL—a requirement as infeasible as it is nonexistent—Abbott's argument would still fail. There is evidence in this case that low levels of exposure to formula can lead to NEC, even though Dr. Spector did not use it to identify a specific threshold dose for the causal association with NEC. For example, Sullivan et al., studied whether a diet of fortifier plus human milk

[5] While the PLC disputes Abbott's contentions, the fact remains that *Abbott* believes the issue is dispositive, thus satisfying the fourth prong.

increased the risk of NEC when compared to a diet of human milk plus a human milk fortifier. *See* No. 1:22-cv-00071, ECF No. 614-57 (Sandra Sullivan et al., *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 156 J. Pediatr. 562 (2010)). Sullivan reported the median percentage of mother's own milk in the bovine arm was 82% (meaning the median percent of consumed CMBF was 18%). *Id.* at Table III. But the range of fortifier on a percentage basis in the bovine arm was 0–62%. *Id.* In other words, there were infants in the bovine arm that received the same amount of cow's-milk-based formula as D.B. And, of course, Sullivan reported the risk of this exposure was RR=2.75 (CI: 1.16–6.52). In other words, D.B.'s diet falls within the parameters of a statistically significant study Dr. Spector considered in his analysis.

The "fit" argument Abbott makes depends on how exposure to formula is measured. This has been a contested issue in this MDL. The parties have presented two possible ways of measuring exposure to formula: as a percentage of the infant's diet from time of birth to time of NEC diagnosis (Abbott's way), or as a percentage of the infant's diet from time of first exposure to formula to time of NEC diagnosis (Plaintiffs' way). During oral argument, the Court questioned the legitimacy of Abbott's position:

> If I've never eaten blueberries before in my life and I eat blueberries and I suddenly get hives, the doctor says, you know, "you may have been having some kind of allergic reaction." He wouldn't say, "okay, but blueberries constitute .01 percent of the things you've eaten over your whole life, so it couldn't be that."

1:22-cv-00232, ECF No. 113 (*Daubert* Hrg. Tr.) at 133:7–12. That approach to measuring exposure makes sense, and the Court should adhere to it.

To state the obvious, exposure to formula occurs when an infant is actually exposed to formula—not when an infant is exposed to *any* type of food. Just like cancer risk from cigarettes is measured from the *start* of cigarette use (*i.e.*, pack years), exposure to formula can be measured only from when an infant is first fed formula. Until the toxin is introduced, there is nothing to measure.

To claim D.B.'s diet was 10% formula, as Abbott has, would sidestep this truth—one so obvious that Plaintiffs' experts never even thought to discuss it—and begin measuring formula exposure before the exposure ever occurred.

Abbott contends the issue of how to measure exposure is "ripe" for resolution, urging the Court to humor its unorthodox theory of exposure. But this Court already ruled on this issue when it excluded Dr. Makuch (Abbott's epidemiologist), noting Dr. Makuch attempted to opine that the peer-reviewed literature established no causal association for any infant whose diet contained less than 25% formula. Ultimately, the Court excluded Dr. Makuch's opinion. In doing so, under the heading "Applicability to Facts of *Etienne* [D.B.'s mother]," the Court framed the exact issue Abbott advances here:

> Abbott has argued that exposure to [cow's-milk-based formula] must be measured by taking the amount of [formula] ingested as a proportion of the infant's total feedings beginning from birth and until the onset of NEC . . . In contrast, Plaintiffs have argued that exposure must be measured "in the days prior to the onset of NEC." . . . Because the court granted summary judgment on different grounds, it did not resolve the proper way to measure exposure to [formula].

No. 1:22-cv-05358, ECF No. 683 (Order), PageID #30046 (citations omitted). After framing the issue, the court noted, "Plaintiffs' motion to exclude Dr. Makuch brings this contested issue to a head." *Id.* Turning to D.B.'s formula consumption, the Court (accurately) held, "but if the court were to include that the proper measure of D.B.'s intake of [formula] would show he received more than 30%, Dr. Makuch's meta-analysis may not help a jury determine whether [formula] did or did not have a causal effect." *Id.* The *only* way to reach this conclusion is to accept Plaintiffs' argument that the appropriate window to evaluate exposure is from when the first exposure occurred—as is done in *every* peer-reviewed study Abbott cites. Abbott cannot point to even one study where the protocol required

weeks of feeding human milk before transitioning to formula. Instead, every study Defendant relies on measured percentage of formula consumption from the time of first exposure to formula.[6]

Although Abbott's current motion was filed four days after the Court issued its Order excluding Dr. Makuch, it was wholly silent regarding that Order and its effect on Abbott's exposure argument. But that is not to say Abbott said nothing. It attempted to convince the Court via letter briefing that the Order was wrong. In that letter brief Abbott raises the exact same argument it raises here (which is the same argument it raised and lost months ago in *Mar*). No. 1:22-cv-00071, ECF No. 686 (Letter from James F. Hurst), PageID #30079 ("And in its March 14, 2025 Omnibus Opposition to Plaintiffs' Motions to Exclude, Master Dkt. 626—without contradiction from Plaintiffs—Abbott stated that 'the undisputed evidence shows that each infant was fed more than 75% human milk: in *Mar*, [R.M.] received ~95% of her nutrition from human milk, and in *Brown/Etienne*, [D.B.] received ~91%.'")[7]; *Id.* ("***Second***, the Court also discussed what it described as the 'strenuously debated' issue regarding the 'proper way to measure an infant's exposure' to formula and noted that Dr. Makuch's 'voice' was 'missing' on that issue… There is a straightforward explanation for that too: Dr. Makuch was responding to Plaintiffs' experts, and those experts never suggested it was appropriate to measure an infant's formula exposure based on either 'the days prior to the onset of NEC'… or, as a potentially conflicting alternative, 'beginning at their first exposure to formula.'"); *Id.* at PageID #30079–80 ("On the contrary, Plaintiffs' own epidemiologist Dr. Spector acknowledged that his causation opinion 'depend[ed] on the percentage of diet that is made of formula'… and then specifically limited his opinion to diets that were 'predominantly' formula, unlike D.B.'s… Dr. Spector has never stated or

[6] For example, Berkhout does collect data from birth to NEC diagnosis because the formula groups—whether full formula or combination of formula and human milk—start that regime *at birth*. Berkhout et al., *Risk Factors for Necrotizing Enterocolitis: A Prospective Multicenter Case-Control Study,* Karger (2018) pp. 278–79. There is no indication that any babies in the formula or combination groups started on an exclusively human milk diet and then supplemented with or completely switched to formula.

[7] This evidence was not, in fact, undisputed. It was the subject of significant dispute at the *Daubert* hearing in March and has arisen on multiple occasions since then.

even implied that what he *really* meant was 'predominantly' formula in 'the days prior to the onset of NEC' or following the 'first exposure to formula.'").

The Court quickly dispatched with Abbott's contention, issuing a Minute Order stating:

> The court now recognizes that the parties agree that the Etienne infant consumed 8,550.4 mL of human milk and 873 mL of Abbott's formula, commensurate with a 90% human-milk diet across all of D.B's feedings prior to the onset of NEC. The court *nevertheless stands by its conclusion* that Dr. Makuch, who examined studies limited to premature infants who consumed more than 75% human milk, should supplement his report with an explanation of why looking at an infant's entire feeding, as opposed to a more targeted range suggested by Plaintiffs, is the appropriate method of measuring an infant's formula exposure to formula.

ECF No. 685 (Minute Entry) (emphasis added).

On September 12, 2025, Abbott finally took steps to resolve this deficiency, filing a Supplemental Report with the Court. But that step is too little, too late. The deadline for production of expert reports in this case has long passed. Given the Court ruled on Dr. Makuch months ago, Abbott's failure to timely supplement the record is dispositive for this case. No. 1:22-cv-00232, ECF No. 105 (Order), PageID #11072–73. Further, unlike with Dr. Spector's Supplemental Report, Defendants were afforded the right to depose him for a second time, *before* filing their Rule 702 motion. The PLC was afforded no opportunity to depose Dr. Makuch again. As such, any opportunity to supplement Dr. Makuch's report in this case has long passed, so there is no evidentiary support for Abbott's contention.

Even so, there will be a time and place to evaluate Dr. Makuch's supplemental report should the Court decide to allow it. Specifically, the Wave II Bellwether Protocol that is being negotiated between the parties contemplates *both* amendments to expert reports and/or new expert reports altogether. So perhaps someday, after the PLC has an opportunity to digest, evaluate, and depose Dr. Makuch, Abbott might fairly request another bite at the apple. But that day is not today, and that day will likely never come because Dr. Makuch's total-feed construct is not viable. In his deposition, Dr. Makuch disavowed any understanding of why the 75/25 dichotomy was relevant or meaningful to

this MDL. No. 1:22-cv-00071, ECF No. 683 (Order), PageID #30046 ("While Abbott's counsel has made forceful arguments in favor of their interpretation of exposure, Dr. Makuch's voice has been missing; his report provides no basis for his decision to limit his search for studies to those involving 75% human-milk diets as it applies to the *Etienne* case."); 1:22-cv-00071, ECF No. 616-12 (Makuch Tr.) at 109:1–24 (explaining that Dr. Makuch's 75%-human-milk standard originated from the facts of a state-court case). Dr. Spector's testimony, in contrast, not only supports measurement of exposure in the days prior to onset but also comments on mechanism:

> **Q**. Do you know how long after *exposure* to preterm formula it causes NEC?
> **A.** Again, it's thought that triggers of NEC take days to – *hours to days* to become fulminant.

ECF No. 616-3 (Spector Tr. Vol. 1) at 37:6–9 (emphasis added). Plainly stated, NEC is triggered by exposure to formula. Including time when an infant was not exposed to formula at all in the measurement of exposure would defy logic.

Undeterred by the Court's observations in its Order excluding Dr. Makuch, or the fact the Court resolved this issue in its September 2, 2025 Minute Order, Abbott continues to pursue its "total feed" argument, citing testimony from Dr. Martin that human milk has ongoing protective effects. But this argument is totally irrelevant. When pressed, Dr. Martin conceded she did not know how long any protection from human milk lasts, let alone how much milk must be consumed to provide a "long lasting" protective effect:

> **Q.** How much protective effect did those 30 days of human milk give that baby?
> **A.** I don't think it's ever been quantified like that. Knowing the biology and physiology of what human milk does, I would have – I would assume a fair amount of protection.
> **Q.** You would assume it, but you don't know, right?
> **A.** Well, I don't think you can do those studies exactly.

ECF No. 616-42 (Martin Tr. Vol. III) at 82:9–19. In other words, Dr. Martin provides no more support for the "total feed" argument than Dr. Makuch did, and certainly does nothing to undermine

this Court's conclusion that feed percentages should not be measured from the date of the actual exposure—a point Abbott's experts (along with its pending motion) remain completely silent on.

IV. Conclusion

Plaintiffs have demonstrated—on multiple occasions—that Dr. Spector's opinions are admissible by a preponderance of the evidence. His opinions are reliable and well-supported by literature and case law, and will help the jury understand the causal relationship between Abbott's cow's-milk-based products and NEC, clearing the Rule 702 bar. His opinions fit the facts of this case and should be presented to the jury. Abbott's motion improperly applies the law, ignores this Court's prior holdings, and should be denied.

Dated: September 25, 2025

Respectfully submitted,

/s/ Timothy J. Becker
Timothy J. Becker
Johnson Becker, PLLC
444 Cedar Street
Suite 1800
St. Paul, Minnesota 55101
(612) 436-1800
tbecker@johnsonbecker.com
Plaintiffs' Co-Lead Counsel

/s/ C. Andrew Childers
C. Andrew Childers
Levin, Papantonio, Rafferty, Proctor, Buchanan, O'brien, Barr & Mougey, P.A.
316 S. Baylen Street, Sixth Floor
Pensacola, Florida 32502
(850) 435-7000
achilders@levinlaw.com
Plaintiffs' Co-Lead Counsel

/s/ Diandra S. Debrosse Zimmermann
Diandra S. Debrosse Zimmerman
DiCello Levitt LLP
420 20th St. N. Ste. 2525
Birmingham, Alabama 35203
(205) 453-6415
fu@dicellolevitt.com
Plaintiffs' Co-Lead Counsel

/s/ Wendy R. Fleishman
Wendy R. Fleishman
Lieff, Cabraser, Heimann & Bernstein, LLP
250 Hudson Street, 8th Floor
New York, New York 10013
(212) 355-9500
wfleishman@lchb.com
Plaintiffs' Co-Lead Counsel

/s/ José M. Rojas
José M. Rojas
Levin, Rojas, Camassar & Reck, LLC
40 Russ Street
Hartford, Connecticut 06106
(860) 232-3476
rojas@ctlawyer.net
Plaintiffs' Co-Lead Counsel